

Patient Information

Fesoterodine Fumarate (FES oh TER oh deen)

Extended-Release Tablets, for oral use

Read the Patient Information that comes with fesoterodine fumarate extended-release tablets before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What are fesoterodine fumarate extended-release tablets?

Fesoterodine fumarate extended-release tablets are a prescription medicine used:

- in adults to treat symptoms of a condition called overactive bladder (OAB), including urge urinary incontinence (leaking or wetting accidents due to a strong need to urinate), urinary urgency (having a strong need to urinate right away), or urinary frequency (having to urinate too often).

It is not known if fesoterodine fumarate is safe and effective in children younger than 6 years of age or with a body weight 55 pounds (25 kg) or less.

Who should not take fesoterodine fumarate extended-release tablets?

Do not take fesoterodine fumarate extended-release tablets if you:

- are allergic to fesoterodine fumarate extended-release tablets or any of its ingredients. See the end of this leaflet for a complete list of ingredients.
- are allergic to tolterodine tartrate tablets or tolterodine tartrate extended-release capsules.
- are not able to empty your bladder (urinary retention).
- have delayed or slow emptying of your stomach (gastric retention).
- have an eye problem called uncontrolled narrow-angle glaucoma.

Before you take fesoterodine fumarate extended-release tablets, tell your healthcare provider about all your medical conditions, including if you:

- have problems emptying your bladder or you have a weak urine stream.
- have any stomach or intestinal problems, or problems with constipation.
- are receiving treatment for an eye problem called narrow-angle glaucoma.
- have a condition called Myasthenia Gravis.
- have kidney problems
- have liver problems
- are pregnant or planing to become pregnant. It is not known if fesoterodine fumarate extended-release tablets will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if fesoterodine fumarate passes into your breast milk. You should talk to your healthcare provider about the best way to feed your baby while taking fesoterodine fumarate extended-release tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal products. Fesoterodine fumarate extended-release tablets may affect the way other medicines work, and other medicines may affect how fesoterodine fumarate extended-release tablets work. Especially tell your healthcare provider if you are taking antimuscarinic, antibiotics, or antifungal medicines.

Know all the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist each time you get a new medicine.

How should I take fesoterodine fumarate extended-release tablets?

- Take fesoterodine fumarate extended-release tablets exactly as your healthcare provider tells you to take it.
- Your healthcare provider may lower your dose of fesoterodine fumarate extended-release tablets if you are an adult with severe kidney problems.
- Take fesoterodine fumarate extended-release tablets with liquid and swallow the tablet whole. Do not chew, divide, or crush the tablet.
- Take fesoterodine fumarate extended-release tablets with or without food.
- If you miss a dose of fesoterodine fumarate extended-release tablets, begin taking fesoterodine fumarate extended-release tablets again the next day. Do not take 2 doses of fesoterodine fumarate extended-release tablets in the same day.
- If you take too much fesoterodine fumarate extended-release tablets, call your healthcare provider or go to an emergency department right away.

What should I avoid while taking fesoterodine fumarate extended-release tablets?

- Fesoterodine fumarate extended-release tablets can cause blurred vision,

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dizziness, and drowsiness. Do not drive, operate machinery, or do other dangerous activities until you know how fesoterodine fumarate affects you.

- Use caution in hot environments. Decreased sweating and severe heat illness can happen when medicines such as fesoterodine fumarate extended-release tablets are used in a hot environment.
- Drinking alcohol while taking medicines such as fesoterodine fumarate extended-release tablets may cause increased drowsiness.

What are the possible side effects of fesoterodine fumarate extended-release tablets?

Fesoterodine fumarate extended-release tablets may cause serious side effects, including:

- **serious allergic reactions.** Symptoms of a serious allergic reaction may include swelling of the face, lips, throat or tongue. If you have any of these symptoms, you should stop taking fesoterodine fumarate extended-release tablets and get emergency medical help right away.
- **inability to empty bladder (urinary retention).** Fesoterodine fumarate extended-release tablets may increase your chances of not being able to empty your bladder if you have bladder outlet obstruction. Tell your healthcare provider right away if you are unable to empty your bladder.
- **central nervous system (CNS) effects.** Talk to your healthcare provider right away if you get any of these side effects: headache, dizziness, and drowsiness.
- **worsening of Myasthenia Gravis symptoms.**

The most common side effects of fesoterodine fumarate extended-release tablets in adults include:

- dry mouth
- constipation

Talk to your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of fesoterodine fumarate extended-release tablets. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store fesoterodine fumarate extended-release tablets?

- Store fesoterodine extended-release tablets between 68°F to 77°F (20°C to 25°C).
- Protect the medicine from moisture by keeping the bottle closed tightly.
- **Keep fesoterodine fumarate extended-release tablets and all medicines out of the reach of children.**

General information about the safe and effective use of fesoterodine fumarate extended-release tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use fesoterodine fumarate extended-release tablets for a condition for which it was not prescribed. Do not give fesoterodine fumarate extended-release tablets to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about fumarate extended-release tablets that is written for health professionals.

What are the ingredients in fesoterodine fumarate extended-release tablets?

Active ingredient: fesoterodine fumarate

Inactive ingredients: FD&C Blue #2, fructose, glyceryl behenate, hypromellose, lactose anhydrous, lecithin soya, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

Pediatric use information is approved for Pfizer Inc.'s TOVIAZ® (fesoterodine fumarate) extended-release tablets. However, due to Pfizer Inc.'s marketing exclusivity rights, this drug product is not labeled with that information.

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